



GloveFAST Aseptic Sterility testing isolators



LABORATORY AND
INDUSTRIAL EQUIPMENT

GloveFAST Aseptic

Faster Isolators for highly sterile applications

GloveFAST Aseptic is the latest isolators for highly sterile applications.

Mainly conceived and designed for IV, parenteral nutrition preparations performed in hospital pharmacies or in Aseptic compounding units inside the hospitals, this unit finds applications also in the pharmaceutical fields when it comes to the need of performing sterility tests in QC labs or biological labs.



RANGE OF APPLICATIONS processing of
■ CIVAS ■ TPN ■ STERILITY TESTS

ECO CONTROLLING SYSTEM - ENERGY EFFICIENCY TECHNOLOGIES FOR A LOW ENVIRONMENTAL IMPACT

The new ECS® microprocessor uses the latest innovative methods of integrated management of all the principal functions of ventilation and filtration - self-regulating the ventilation system by compensating for the increased pressure drops of the filters and restoring power balance.

Combining the use of DC motors, dimmable LED lights and certified low pressure-drop filters, the new ECS® controlling system optimizes power consumption, reducing CO₂ emissions into the environment.

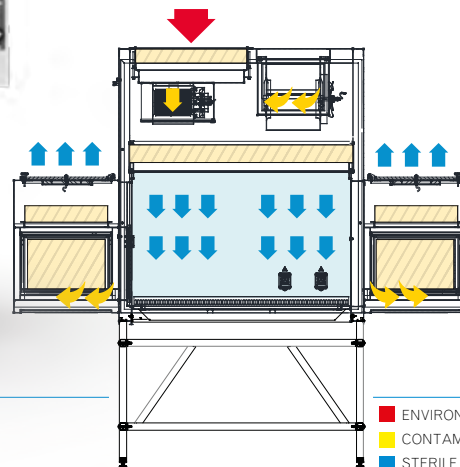


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SAFETY WITHOUT COMPROMISES

Faster GloveFAST Aseptic isolators are positive pressure devices which separate the pharmaceutical products being handled in the work area from the operator and the surrounding environment which are the first source of contamination. **Faster GloveFAST Aseptic units offer then the highest protection to the products that are handled inside the work chamber.** Primarily conceived for safe aseptic handling of non-hazardous materials such as TPN, IV preparation **Faster GloveFAST Aseptic** is positive isolator in **Class 2 as per ISO14644-7** with leak rate level measured in 16 Pa/minute with a real unidirectional airflow providing a **Class ISO 3 in terms of cleanliness level according to ISO 14644-1 or EC GMP Grade A.**



WORKING PRINCIPLES

Room air is aspirated through an H14 HEPA filter located at the top of unit and is pushed into the plenum of the unit. From here is pushed in the working area through the main downflow filter where a positive pressure ambient is created as well as laminar flow conditions. Through the slots of the work surface, the air pass then in the return channel located at the back of the work chamber. Part of it is then recirculating in the upper part and part is released towards the transfer

hatches. The pressurized air reaches then the transfer hatch chamber through the H14 HEPA located in the back wall of each transfer hatch. Positive pressure hatch maintains a dynamic protection against possible contamination coming from the room when the outer hatch door is opened. The air is then exhausted at the top of each hatch prior being filtered by the last H14 HEPA filter located at the top of the hatches.

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THE BEST FILTRATION EVER

Differently from many other units available in the market for the same type of use, the unit offers a very first level of H14 filtration in aspiration at the top of the unit providing then an immediate high reduction of airborne contamination. Real unidirectional Laminar Flow conditions are created then thanks to a H14 HEPA filter (High Efficiency Particulate Air) covering the entire work area and to 7° sloped front and back. The transfer hatches are also filtered by means of 2 HEPA filters H14 and G4 prefilters.

DIMMABLE LED LIGHTS

allowing power consumption reduction and adjustable to fit different users needs.



ROUND GLOVEPORTS The front visor is equipped with either 2 or 4 integrated glove ports of 300/250 mm diameter allowing great comfort to the user especially during cleaning operations.



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MAIN FEATURES



IP 66 ELECTRICAL SOCKETS

2 x IP 66 electrical sockets for total protection against liquid splashes.



REMOVABLE WORK SURFACE

Work Surface in stainless steel AISI 316L is easily removable for routine cleaning and disinfection procedures. As standard supplied with multipiece perforated work surface, it can come also with a variety of other solutions solid multipiece, in one piece ect. Work chamber entirely made of stainless steel 304.

SMOOTH SURFACE

without crevice as per GMP requirements.



UNMATCHED NOISE LEVEL

With most of the competitors sounding extremely loud, GloveFAST Aseptic offers an incredibly low noise level.

The on field experience proved that the decommissioning of competitors' isolators and installation of the new GloveFAST Aseptic brings to a substantial reduction of the noise level in the room.

SAFETY EVERY DAY

Automatic Pressure Decay Test:

If the ATV valve has been included in the isolator configuration, **users can be everyday sure that the isolator is fully compliant with the expectations and ready to work in full safety**, without having to wait the next preventive maintenance.

In case the pressure decay is higher than the set threshold the display will show "Pressure Test Fail".

In case the pressure decay is lower than the set threshold the display will show "Pressure Test Pass".

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CONSTRUCTIONS FEATURES

CONSTRUCTION

Full body of the unit and transfer hatches made in epoxy painted steel coated with Alesta® Dupont anti-microbial painting. Full AISI 304L stainless steel body carcass and hatches available as option.

WORKING SURFACES

Fully made in AISI 316L stainless steel with scotch brite finishing.

Back and side walls in AISI 304L stainless steel.

TRANSFER HATCHES

GloveFAST Aseptic transfer hatches are D2 type according to ISO 14644-7.

The hatches are fitted with an outer door and a top lid made of safety opaque glass.

Inner and outer hatch doors are interlocked.

Separated timers for loading and unloading hatches can be set as per customer request.



FILTRATION

Filtration is provided by seven levels of absolute filters H14 HEPA/ULPA with typical efficiency of 99.995% MPPS according to CEN EN 1822 as well as 99.999% conforming to IEST-RP CC00 1.3 USA. All the filters are low pressure drop certified H14 HEPA/ULPA filters.

DEHS RAPID TEST PORTS

The Isolator is fitted with a number of test ports allowing the HEPA filters to be tested individually.

SLEEVE+GLOVES

The polyethylene glove ports of 300 mm/250 mm host a CSM sleeves connected to neoprene gloves by means of PVC cuff ring.

Glove and sleeve can be replaced separately thus saving money for the end user.



AIR QUALITY

Air cleanless in Class ISO 3, according to ISO 14644-1

Vertical, unidirectional flow (laminar flow) in the work zone is 0,45 m/s. Inflow velocity in case of sleeve breeching is $\geq 0,7$ m/s (as per ISO 14644-7).

GLASSES

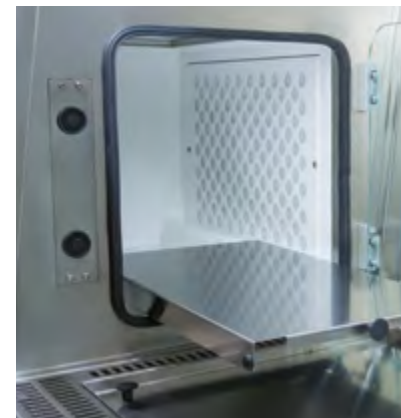
Front window made of 8 mm safety glass is framed in an aluminum frame. Internal and external transfer hatch doors are made of safety glass. The frontal view-screen is slanted with top hinges and gas struts that allow full opening for loading and unloading of bulky tools.



TRANSFER HATCHES SLIDING WORK SURFACE

Stainless steel AISI 316L sliding tray in each transfer hatch ease the transfer of materials inside/outside the working volume.

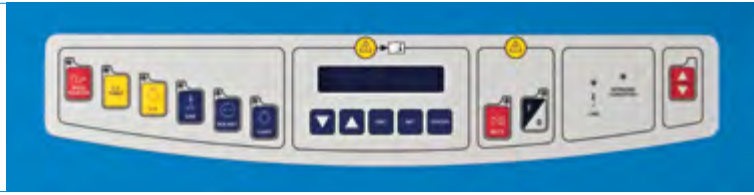
The trays are removable for sterilization processes in autoclave.



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THE USER-FRIENDLY
PRACTICAL
KEYBOARD



AUDIO VISUAL ALARMS PROVIDED FOR

- out of range laminar airflow velocity
- low operating pressure
- saturation of H14 HEPA/ULPA filters
- blockage in the exhaust duct
- motor malfunction
- power failure
- leak rate test failure

ECS® MICROPROCESSOR BASED MONITORING SYSTEM:

full status report provided on the 2-line digital display via the new generation microprocessor which controls control all functions and automatically compensate motor power reduction that may happen due to the progressive clogging of the filters, ensuring that steady laminar flow velocity and safety are kept.



THE USER-FRIENDLY PRACTICAL KEYBOARD

and the rear-lit LCD will continuously display all required data keeping the user constantly informed of the cabinet working conditions in particular:

- display of laminar airflow velocity
- display of inside and outside temperature
- display of residual lifetime of H14 HEPA/ULPA filters, UV Lamp (if fitted)
- display of total number of hours of operation
- display of saturation level of H14 HEPA/ULPA filters
- operating pressure
- motors power



COMPLIANCE

FILTRATION	AIR CLEANLINESS	CONTAINMENT	ELECTRICAL SAFETY
EN 1822/ IEST-RP-CC00 1.3	ISO 14644-1	ISO 14644-7	EN 61010-1/ IEC 61010-1

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TOP QUALITY

- Air quality in grade A (unidirectional Laminar Flow) as per EU-GMP Guide within the entire work zone
- Easy cleaning of inner and outer surface
- Automatic pressure decay test (via optional ATV valve) with results of the test stored in the isolator back up memory.
- Positive operating pressure (+75 Pa) with laminar airflow and actively regulated blowers
- Aseptic glove-changing system
- Easy monitoring of all parameters, test and maintenance
- Ergonomically designed for easy operation, good visibility and high operators' comfort
- High air-change rate within the work zone and the transfer hatches for rapid clean-up of contaminated air
- Foot switch controlled inner doors



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HANDS FREE

Inner and outer doors of the transfer hatches are hinged and operate by means of footswitch. As option, an electrical vertically sliding system can be provided for inner doors.

The outer doors open from left to right or viceversa (depending on which hatch). As option and in the 3 way hatch they can be opened upwards.



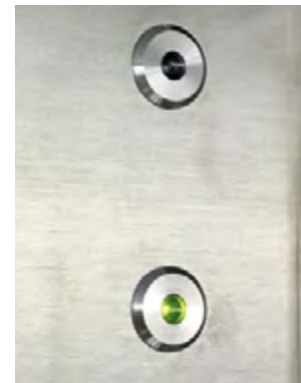
standard hinged inner door



electrical sliding inner door (optional)



foot switch



LED indicators for inner hatch door status in the internal back wall

POWER IS NOTHING WITHOUT CONTROL

The diagram illustrates the RemoteFAST remote control system. It shows a 'Customer' workstation on the left and a 'Service' workstation on the right. A wireless signal icon connects the two workstations, indicating remote communication. The Customer workstation is a blue cabinet with a monitor and keyboard. The Service workstation is a computer monitor and keyboard.

The optional remote control (RemoteFAST) allows FASTER service engineer to monitor isolator's functions as well as making preliminary diagnosis in the event of breakdown.

This allow local service engineers to visit customer site with the solution already in their pocket.

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OPTIONAL

OPTIONAL EXTRAS

The list of optional extras available for GloveFAST Aseptic is quite wide. The most common are listed here below:

- Stainless steel hanging rail with six hooks
- Compressed air, vacuum and nitrogen service taps
- H₂O₂ pipework for connection to most common brands of VHP generators like Steris, Bioquell with specific communication protocols developed
- Electrically operated adjustable support stand
- Easy-Change Cuff Ring System (Push/Push)
- CCTV for documented/traceable process
- Glove/sleeve test disc with digital manometer
- RJ 45/RS 232/USB Interface ports
- Temperature and humidity sensors
- Sealed monitor screen in the backwall
- Multi-functional touch-display (size 7")
- Intercom
- ATV valve on top of the unit for automatic leak rate test
- ATV valves on the hatches in replacement of the standard lids for automatic leak rate test
- Inflatable gaskets for superior isolation during VHP decontamination
- Rapid decontamination hatch
- Integration of peristaltic pumps (Sartorius, Merck Millipore)
- Easy swap positive/negative pressure



- Single hatch version
- Electrical inner hatch doors
- 19" cleanroom touch screen
- Isokinetic probe for particle monitoring
- Display of hatch pressure





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CUSTOM MADE SOLUTIONS

A wide range of customization is available, from rapid decontamination hatch integrating VHP generators to peristaltic pump in order to perform sterility tests procedures.



TECHNICAL SPECIFICATION



Description	GloveFAST Aseptic			
	2-4-2	2-5-4	2-6-4	
<i>Isolator dimensions</i>	<i>Unit</i>			
Outer dim. (WxDxH) complete	mm	2510x870x2300	2815x870x2300	3120x870x2300
Inner dim. (WxDxH) work chamber	mm	1192x580x740	1497x580x740	1802x580x740
Gloves material	Neoprene			
Sleeves material	PVC			
Sleeve dimensions	Dimensions at wrist 90 mm-Glove port Ø 300/250 mm			
<i>Electrical connection & weight</i>				
Weight (approx. kg)		450	480	520
Lighting level (Lux)			≥ 2000	
Noise level (dB(A))		51	53	56
<i>Working parameters</i>				
Operating pressure			+75 Pa	
Downflow air speed			0,45 m/s	
Exhaust Flow rate			300 m ³ /h	



Striving everyday to improve our environmental performance, FASTER developed environmental procedures are founded on three guiding principles:

- Protect the Environment for present and future generations: manufacturing low energy consumption equipments
- Reduce risks and improve efficiencies
- Introduce improved technology and processes



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